Northwest Center for Outcomes Research in Older Adults: A VA HSR&D Center of Excellence

Emblem: "Soul Catcher" ...a Northwest Coast Indian symbol used to ward off spirits that brought physical or mental illness. Artist: Marvin Oliver.

Medical Centers - Seattle, WA & Portland, OR **January 2004**

Affiliated with the University of Washington School of Public Health and Community Medicine, Seattle,WA & Center for Health Research (Kaiser Permanente), Portland, OR

Effects of Ethnicity and Nephropathy on Lower-Extremity Amputation Risk Among Diabetic Veterans

Bessie Young, MD MPH, Charles Maynard, PhD, Gayle Reiber, MPH PhD, Edward Boyko, MD MPH

Introduction

The diabetic foot syndrome, resulting in lower extremity amputation, contributes to the enormous morbidity and mortality of diabetes mellitus, and results in increased patient disability, decreased quality of life and increased healthcare costs. We conducted a retrospective cohort study to examine ethnic differences in the risk of lower extremity amputations in a population of diabetic patients with and without renal disease who received treatment in a national comprehensive healthcare system.

Methods

Subjects with diabetes mellitus who received primary care within the U.S. Veterans Affairs (VA) Health Care System during fiscal year 1998 (FY98) were selected for a retrospective cohort study. To identify patients with diabetes, we utilized the following national Veterans Health Administration (VHA) databases: the Patient Treatment File (PTF), the Outpatient Care File (OPC), and the Beneficiary Identification and Record Locator System (BIRLS) death file, a database that contains name, social security number and date of death. The BIRLS death file has been shown to have a 94.5% ascertainment of death, which compares favorably to that of the National Death Index (96.7%). For fiscal year 1998, all veterans with a diagnosis of diabetes were identified by the presence of at least one outpatient or inpatient visit with an ICD-9-CM diagnosis code of diabetes (250.XX). We required a total of 3 or more visits for that year for inclusion into the study. ICD-9-CM diagnosis codes were used to extract hospitalizations from the PTF and the OPC.

Characteristics of interest included age, ethnicity, gender, region, hospitalizations, service connected disabilities and total number of visits. Comorbid conditions such as coronary artery disease, hypertension, stroke, cancer, chronic obstructive pulmonary disease (COPD), and depression were also identified. The presence of diabetic renal disease was considered as a potential exposure, and was identified in the population at the beginning of the study period by the use of ICD-9-CM diagnosis codes.

All lower extremity amputations were identified for fiscal year 1998 by ICD-9-CM procedure codes 84.11 through 84.19. Traumatic amputations were excluded. Multiple amputations that occurred on the same day were considered as one procedure.

We conducted statistical analyses to determine frequencies of distribution of covariates and associations of exposures with amputations for the diabetic veteran population. Data analyses were performed using the STATA 7.0 (College Station, TX) software statistical package. Statistical significance was determined by the independent student t-test for continuous data and the chi-squared test for categorical data. Cox proportional hazard modeling was used to estimate the risk of amputation, as modeled for censored failure times. Individuals were censored for death and the end of the study period. The hazard, or the instantaneous probability of an event, was modeled as a function of the predictor covariates.

Results

Of the 429,918 veterans identified with diabetes for fiscal year 1998, 11,794 had one or more amputations between 1989-1999. Of those identified, 8,388 had amputations between 1989 and October 1997, while 3,289 veterans underwent incident non-traumatic lower extremity amputations from October 1, 1997 to September 30, 1998. Veterans with amputations

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were in general older (66 years. vs. 64 years, p<0.001), more likely to be male (99.3%), more likely to belong to an ethnic minority group and less likely to have service connection for their care at the VA compared with veterans without amputations. Furthermore, veterans with amputations were more likely to have comorbid conditions such as hypertension, cardiovascular disease, stroke or COPD. In addition, unadjusted 12-month mortality was significantly higher in veterans with amputations compared to those without amputations (18.5-21.8% vs. 5.9%, P<0.001).

Diabetic veterans with prevalent amputations were more likely to have a diagnosis of renal disease, while the prevalence of diabetic renal disease was increased in diabetic veterans with amputations compared to those without amputations (29.6% vs. 9.8%, P<0.001). Among veterans with amputations, diabetic ESRD was the most frequent renal diagnosis, which was followed by diabetic nephropathy not yet on dialysis and acute renal failure. Interstitial nephritis, renal cell cancer and other renal diseases were rare overall, but similar in veterans with and without amputations.

In order to determine risk factors for incident lower extremity amputations, Cox proportional hazard models were generated. Native American veterans, who comprised the smallest minority population nationally, had the highest risk of lower extremity amputation compared with white veterans (RR=1.74, 95% CI 1.39-2.18). African Americans had a 1.4 fold higher risk (95% CI 1.31-1.48), while Hispanic veterans had a 1.2-fold higher risk of amputation (95% CI 1.20-1.38) when compared to white veterans. We further found that Asian veterans had a 69% lower risk of amputation when compared to whites (RR = 0.31, 95% CI = 0.19, 0.50) in models adjusted for age, region, service-connected disability cardiovascular disease, hypertension and COPD.

Although women veterans comprised only 2.6% of the total population, and only 1% of veterans with amputations, their risk of amputation was 69% lower than that of diabetic men (RR = 0.31, 95% CI = 0.25 - 0.39). Adjustment for region, service connection, age, comorbid conditions and the presence of renal disease did not substantially alter that risk.

Significant differences were found when the risk of amputation was evaluated for those with prevalent renal disease. Diabetic nephropathy increased the risk of amputation 3.4-fold while diabetic ESRD increased the risk 3.8-fold after adjustment for age, gender, region, comorbid conditions and service connection.

Discussion

In this national cohort of veterans with diabetes, we found that certain ethnicities were associated with an increased lower extremity amputation risk. In addition, the presence of diabetic nephropathy increased the amputation risk 3-fold, when individuals with renal disease were compared to those without renal disease. Diabetic individuals have a 10 to 15 fold greater risk of lower extremity amputations than non-diabetic individuals. In addition, the risk for amputation is higher in males and increases with age. Various population-based studies have identified consistent risk factors for lower extremity amputations. These risk factors include glycemic control, duration of diabetes, blood pressure control and history of foot ulcers. Even though ethnicity has not been found to be a consistent risk factor for amputations, analyses of association of ethnicity with amputation may be confounded by differing degrees of access to care or the presence of hypertension. In this cohort study where access to care was comparable, ethnicity was found to be an independent predictor of amputation.

Patients with diabetes and ESRD are at much higher risk of amputation compared to the non-dialysis population. Eggers and colleagues reported that diabetic individuals with ESRD have a 10-fold higher of amputations compared to the general diabetic population, the risk of which was increased for African Americans and Native Americans. In a clinic-based study, Griffiths et al found that impaired renal function was an independent risk factor for diabetic lower extremity foot ulceration, but renal function increased neither the severity nor the duration of the lesion. Hill and colleagues reported that ethnicity and ESRD were significant risk factors for lower extremity complications such as amputations, foot ulcers and infections. In the present study, we demonstrate an increased risk of lower extremity amputation associated with diabetic nephropathy prior to the initiation of dialysis, and confirm the increased risk of lower extremity amputation in diabetic individuals with ESRD.

Our study has several limitations that must be addressed. First, results obtained were for the veteran population, and as such may not be applicable to the general US population. However, given this limitation, the data illuminate differences in risk of amputation when access to care is not the primary issue. The VA system represents the largest integrated healthcare system in the US and has the capacity to institute changes in healthcare policy rapidly. Although care received by patients in a non-VA setting may differ from that received within the VA, outcomes appear to be similar.

In conclusion, our findings suggest that certain ethnic minority diabetic patients are at increased risk of lower extremity amputation despite comparable access to medical care. The increased amputation risk found was independent of underlying renal disease, cardiovascular disease, COPD or hypertension. Additional prospective research is needed to investigate which risk factors may contribute to the develop-

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ment of microvascular disease in these populations. From the clinical prospective, vigilant monitoring for the development of the diabetic foot syndrome in patients with diabetic nephropathy and those from certain ethnic minority groups may be warranted.

Excerpt taken from:
Young B, Maynard C, Reiber G, Boyko E. Effects of ethnicity and nephropathy on lower-extremity amputation risk among diabetic veterans. Diabetes Care 2003; 18:196-202.

HSR&D 2003 PUBLICATIONS

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FELLOWS' PROFILES

Duncan Campbell, PhD

Duncan, a first-year postdoctoral fellow, graduated in 1991 with a Bachelor's degree in Psychology from the University of North Carolina at Chapel Hill. After a failed attempt at rock-n-roll stardom, he began a degree program in Clinical Psychology at Washington State University. As a graduate student, Duncan investigated the interactions among personality-based diatheses and protective factors in depressive illness. He received his PhD following a clinical internship at the Seattle VA Puget Sound Health Care System in 2002-2003.

Duncan's research in HSR&D investigates social psychological processes, depressive illness, and depression management in primary care. Under the mentorship of Ed Chaney, PhD, Duncan is developing a study that will investigate stigma regarding psychiatric care in VA primary care clinics.

Duncan's wife, Kimberly, is trained as an Art Therapist and works with children through Seattle Mental Health, a nonprofit agency. Duncan and Kim love living in Seattle and the Pacific Northwest. In addition to keeping abreast of trends in college radio and independent music, they make frequent trips to the outdoors and are regular consumers of antiques and the 'junk' of others.

Brian Keeffe, MD

Brian is a first year research fellow in HSR&D. Brian was born and raised in Portland, Oregon. He completed his undergraduate education at Georgetown University in Washington DC, where he pursued a liberal arts education and majored in both English and economics. After completing his post-baccalaureate science courses at the University of San Francisco, he returned to Georgetown University for his medical education. Brian then moved on to internal medicine training, which he completed in 2001 at Stanford University. He currently is in the third year of his cardiology fellowship at the University of Washington, which he is combining with his HSR&D fellowship.

Brian's research interests revolve around quality of care in cardiovascular disease. Specific areas of focus include secondary prevention of atherosclerotic vascular disease and studies aimed at improving guideline adherence in coronary artery disease and congestive heart failure.

Brian is married to Kristin Keeffe, an attorney in Kirkland. Their son Miles is 16 months old, and they are expecting another baby boy in April.

Ryan Chew, MD

Ryan is a first year ambulatory care fellow in HSR&D. He attended the University of California, Davis and received his medical education at Northwestern University Medical School. Seduced by a coffee table book of the northwest, Ryan moved to Seattle for his residency and chief residency in Internal Medicine at the University of Washington. Wanting to learn more about research methods, he decided to pursue further training in health services research as an HSR&D fellow.

While in medical school, Ryan studied the impact of practice guidelines on clinical and cost outcomes of delirium. His current research interests have expanded to include exploring quality of life and care for patients living with chronic hepatitis B.

Ryan and his wife, Momoko, were recently married and enjoy their weekends together watching pop music videos with their affectionate orange tabby cat, Poo, who does nothing but does it extremely well.

Francine Wiest, MD MPH

Francine is a third year fellow in HSR&D after completing two years as a VA Robert Wood Johnson Clinical Scholar. She attended Harvard-Radcliffe College and then spent a year outdoors working in the rainforest of Papua New Guinea, the woods of Vermont, and on a former sugar plantation in St Christopher & Nevis. She returned to school, receiving her medical degree from Columbia College of Physicians & Surgeons, and then went on to train in internal medicine at the Massachusetts General Hospital.

Francine was born in Seattle so she was delighted to return to the Northwest for her fellowship training. She has a diverse array of research interests, and has focused primarily on two quality of care issues: the treatment of chronic stable angina in VA patients and the impact of fatigue on resident physicians. Francine is also very active in the medical education community, serving as the resident/fellow representative on the American Medical Association's Council on Medical Education, and on the American College of Physician's Education Committee. She also completed the University of Washington's Teaching Scholars program in addition to the Master of Public Health degree in community medicine and health services.

Finally, to really keep her on her toes, Francine and her husband James had a baby boy, Jasper, last year. Outside interests previously included birdwatching, gardening, and cooking, and now incorporate carpentry (child-proofing), reading (Goodnight Moon), and juggling (everything).

Here is Vincent Fan at about 11,000 feet after hiking to the Haute Route in Southern Switzerland.

Vincent Fan, MD MS

Vincent Fan joined the Health Services Research and Development Center of Excellence at the VA Puget Sound Health Care System (VAPSHCS) as an investigator in July, 2003. He initially arrived in the Pacific Northwest from Minnesota in 1995 in order to start his residency in Internal Medicine at the University of Washington. After residency, Vincent then joined the VAPSHCS for a two-year General Internal Medicine fellowship in the division of HSR&D and obtained a master of public health degree in epidemiology. Because of his interest in chronic lung disease, he returned to the University of Washington as a Pulmonary and Critical Care fellow, and completed this fellowship in June, 2003.

Vincent's research interests are focused on the study of chronic obstructive pulmonary disease (COPD) among veterans, and the development of interventions to decrease COPD exacerbations. He has received a Career Development Award from VA to develop a staging method to predict exacerbations and hospitalizations among patients with COPD. During his General Medicine and Pulmonary fellowships, Vincent has worked with his mentors Stephan Fihn and Randy Curtis to study the use of patient-derived functional status measures to assess disease severity and the risk of adverse outcomes such as hospitalizations and death. Recently, given the recent controversy surrounding the pharmacologic treatment of COPD, in collaboration with David Au and Chris Bryson, Vincent undertook a study that showed that inhaled corticosteroids did not reduce the risk of death. He is also interested in the impact of comorbid illnesses among general internal medicine patients, and the development of comorbidity adjustment instruments.

Since his arrival in Washington, Vincent has not escaped the lure of the outdoors, spending much of his free time exploring and hiking throughout the Cascades and Olympic mountains.

Northwest HSR&D Center of Excellence

Stephan D. Fihn, MD MPH
Director, HSR&D
Susan C. Hedrick, PhD
Associate Director, Seattle Site
David H. Hickam, MD MPH
Associate Director, Portland Site
David H. Au, MD MS
Investigator
Katharine A. Bradley, MD MPH
Investigator
Edmund P. Chaney, PhD
Investigator
Michael K. Chapko, PhD
Investigator
Research Review Coordinator
Jason A. Dominitz, MD MHS
Investigator
Vincent S. Fan, MD MPH
Investigator
Chaun-Fen Liu, PhD
Investigator
Matthew L. Maciejewski, PhD
Investigator
Information Dissemination Coordinator
Charles Maynard, PhD
Investigator
Gayle E. Reiber, MPH PhD
Investigator
Director, PhD Postdoctoral Fellowship
Anne E. Sales, MSN PhD
Investigator
Bevan Yueh, MD
Investigator
Xioa-Huo (Andrew) Zhou, PhD
Investigator
Jane Summerfield
Administrative Officer
Connie Nakano
IRB Coordinator
Monica Hayes
Staff Assistant
Greg Gilbo
IT Systems Specialist

HSR&D Newsletter

Contributions for the Northwest HSR&D COE Newsletter should be sent to:

HSR&D Newsletter (152) Main Office: (206) 764-2430
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VA Puget Sound Heatlh Care System
1660 S. Columbian Way
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HSR&D Web site: http://www.hsrd.seattle.med.va.gov

HSR&D Deadlines

Local deadline for proposal review is two weeks prior to Research Review Committee meeting. Local Review Committee meets on 1st Friday of each month. Notify Michael Chapko at (206) 764-2821 to be included on review agenda.

VACO Deadlines

Letters of Intent (LOI): Cutoff date for Spring 2004 round is 3/31/04. Guidelines found in VHA Handbook 1204.01.
Investigator-Initiated Research (IIR) and Nursing Research Initiatives (NRI) Proposals: Full application due June 15. An approved LOI is required prior to submission. Guidelines found in VHA Handbook 1204.01.
Research Career Scientist Awards: March 1 and September 1. Guidelines found in VHA Handbook 1204.02.
Career Development Awards: Due February 15 and August 15. Must have approved LOI prior to submission; due November 1 and May 1. Guidelines found in VHA Handbook 1204.02.
Under Secretary's Award for Outstanding Achievement in Health Services Research: Submissions due in VACO October 1. Guidelines found in VHA Handbook 1204.04.

For current guidelines and forms, please refer to www.va.gov/resdev

Phone Listings for HSR&D Service, VA Central Office

Director - John Demakis, MD	(202) 254-0207
Deputy Director - Shirley Meehan, MBA PhD	(202) 254-0208
Management & Program Analyst - Mary Jones	(202) 254-0210
Assistant Director, Research Initiatives & Analysis - Jay Freedman, PhD	(202) 254-0249
Career Development Program Manager - L. Robert Small, Jr.	(202) 254-0219
FAX Number	(202) 254-0461

WHAT'S HAPPENING AT THE NW HSR&D CENTER OF EXCELLENCE

Newly Funded HSR&D Projects for FY 2004

Improving the Quality of End-of-Life Communication for Patients with COPD (IIR#02-292), David Au, MD MS, PI. This is a randomized, controlled trial of a multifaceted intervention to improve communication about end-of-life care and treatment preferences for patients with airflow limitation (COPD).

Improving Management of Chronic Stable Angina (IHI#02-062), Stephan D. Fihn, MD MPH, PI. This multisite randomized trial at 4 VAMCs is designed to evaluate the effectiveness of a collaborative care model in managing patients with chronic stable angina.

Assessing Practice Variation in Long Term Care Referrals (IIR#02-228), Susan Hedrick, PhD, PI. This study will assess current practice of long-term care referral in VA, building on the new uniform VA form, the Geriatrics and Extended Care Referral Form and focus group results. The results will be used to develop interventions to increase the likelihood that referrals are made to home and community-based care programs.

VA Prescription Drug Co-payments and Veterans with Diabetes or Hypertension (IIR#03-200), Matthew Maciejewski, PhD, PI. This study will assess the relationship between an increase in VA prescription drug copayments and three classes of outcomes: medication use, health, and cost/utilization.

New HSR&D Staff

Vincent Fan, MD MS, our newest Career Development Awardee, is highlighted in our Staff Profile page. Dr. Fan's interests include use of clinical databases to assess effectiveness and toxicity of treatments for pulmonary disease. Connie Nakano, has come onboard as our IRB Coordinator, a new position created for the Center of Excellence. Connie will help us develop a coordinated approach to assuring full compliance with regulations for protection of human subjects and their privacy.

New ORD Guidelines for Letters of Intent

Biomedical Laboratory R&D (BLRD) and Clinical Science R&D (CLRD) Merit Review Letter of Intent formats have changed. Please refer to http://www.va.gov/resdev/fr/forms.cfm for guidelines.

HSR&D will gradually adopt this new format, but use old guidelines until 4/1/04. Here are websites for details:

http://www1.va.gov/resdev/funding/timeline_spring04.cfm

http:www1.va.gov/resdev/fr/merit_rev_loi_format_010104.pdf

http://www1.va.gov/resdev/fr/forms.cfm

2004 HSR&D National Meeting

"Meeting the Changing Needs of Veterans: The Quality/Cost Equation," March 9-11,2004. Marriott Wardman Park Hotel, Washington, DC. For general information, contact Karen.Hickey@med.va.gov.

Applicants Wanted for HSR&D PhD Postdoctoral Fellowship Program

Fellows engage in full-time research and related educational activities. Faculty provides expertise in areas of interest including clinical epidemiology, biostatistics, ambulatory care, outcomes research, psychometrics, health economics, quality of care, geriatrics, long-term care, ethics and health policy.

Statement of research interests, specific aims for a VA relevant research project, identification of a local faculty mentor, curriculum vitae and three letters of reference should be sent by March 1, 2004 to: Gayle Reiber, MPH PhD, HSR&D, VA Puget Sound Health Care System (S-152), 1660 S. Columbian Way, Seattle, WA 98108, (206) 764-2089, or email reiber@u.washington.edu.

Future Plans for NW Center for Outcomes Research in Older Adults

Taken from 2003 Annual Report:

- Initiate development of distance learning programs and special courses for investigators interested in acquiring expertise in basic and advanced methods in health services research
- Expansion of our biostatistical unit with emphasis on advancing statistical methods
- Addition of at least one new physician investigator
- Increased collaboration with other Centers of Excellence

6th Annual Epidemiology and Biostatistics Summer Session June 21 - 25, 2004, University of Washington, Seattle, WA

Courses for this annual summer session are designed to provide the latest information on biostatistical and epidemiologic methods to professionals working in clinical, research and public health settings; and to provide relevant examples that illustrate the application of these principles and methods.

Course offerings include: implementation research, clinical measurement, medical diagnostics, epidemiologic methods, general biostatistics, applied logistic regression, applied survival and longitudinal data analysis, multilevel models, genetic epidemiology, and statistical methods for molecular/genetic epidemiology.

For a brochure and application, contact: Carrie McCloud, CPS, Program Assistant, Seattle Epidemiologic Research and Information Center, Phone: 206-764-2773, Fax: 206-764-2563, eric@med.va.gov.